



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443-9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: Membership Forms for Organ Procurement (OPTN) and Transplantation Network OMB No. 0915- 0184 – Revision

Abstract: Membership in the OPTN is determined by submission of application materials to the OPTN (not to HRSA) demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, et seq., the OPTN final rule, OPTN Policies, and OPTN Bylaws. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b–8 (section 1138) requires that hospitals in which transplants are performed by members of, and abide by, the rules and requirements of the OPTN (that have been approved by the Secretary of HHS) as a condition of participation in Medicare and Medicaid.

Need and Proposed Use of the Information: The application materials are needed to ensure that all members and prospective members of the OPTN submit evidence that they meet the required qualifications for membership. These materials provide the OPTN with information to permit the OPTN to confirm and demonstrate that applicants meet OPTN membership application requirements and to create a record of the application review process and resulting actions for consideration by the Secretary of HHS if an applicant subsequently appeals a membership rejection by the OPTN.

This is a request to revise the current OPTN data collection associated with transplant hospitals, organ procurement organizations, transplant histocompatibility laboratories, medical/scientific and public organizations, business organizations, and individuals to meet or sustain requirements for OPTN membership to include data collection forms for OPTN member hospitals requesting HIV Organ Policy Equity (HOPE) Act Variances and Kidney Paired Donation Pilot Program (KPDPP) contact update form. This revision also includes changes to the existing OMB data collection forms. HRSA is submitting the following changes to the Membership forms to clarify requirements and eliminate redundancy while adding more explanatory language and instruction to the applications, which include:

- 1) Adding two new data collection forms for HOPE Act Variance Request and KPDPP contact update form. The HOPE Act Variance Request is for any OPTN member

transplant program that wishes to start a variance to receive HIV-positive organs for their HIV-positive patients. The KPDPP contact update is a form that indicates contact information for programs participating in the KPDPP.

2) Adding three standalone forms for revised data collection: Primary Program

Administrator, Primary Data Coordinator, and Additional Surgeon and Physician. All three of these forms include data previously collected on other OMB- approved forms in this package but now will be standalone forms for greater ease of use for the applicant.

- The Primary Program Administrator data collection form includes data previously collected in each organ-specific application form. Users will only have to complete one form of the proposed Primary Program Administrator serves in that role for multiple programs.
- The Primary Data Coordinator collection form includes data previously collected in each organ-specific application form. This form will be used for organ procurement organizations, histocompatibility lab members, and organ transplant programs so that one standalone form will serve all three member types.
- The Additional Surgeon and Physician data collection form includes data previously collected in the Certificate of Assessment and Program Coverage Plan (COA/PCP) Membership Application form. Users will only have to complete one form if the proposed Surgeon and Physician serve in that role for multiple programs.

The organ-specific application forms have been revised to include the information found in the Certificate of Assessment and Program Coverage Plan Membership Application (COA/PCP). The information found in the COA/PCP has been embedded into all of the organ-specific application forms, negating the need for an independent data collection form.

Likely Respondents: New and existing transplant hospitals, organ procurement organizations, histocompatibility laboratories, medical/scientific organizations, public organizations, businesses, and individual members.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The total burden hours in the OMB inventory increased by 898 hours from the previously OMB-approved data collection package from August 20, 2020. This increase is due in part to including new membership forms.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents ¹	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
OPTN Membership Application for Transplant Hospitals	251	0.28	70	4	280
OPTN Membership Application for Kidney Transplant Programs	234	0.56	132	8	1,056
OPTN Membership Application for Liver Transplant	143	0.59	85	13	1,105

Programs					
OPTN Membership Application for Pancreas Transplant Programs	120	0.26	32	13	416
OPTN Membership Application for Heart Transplant Programs	145	0.34	50	20.5	1,025
OPTN Membership Application for Lung Transplant Programs	72	0.64	46	9	414
OPTN Membership Application for Islet Transplant Programs ²	19	0	0	5	0
OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	43	0.98	42	15.5	651
OPTN Membership Application for Intestine Transplant Programs	21	0.19	4	11	44
OPTN Membership Application for Organ Procurement Organizations (OPOs)	57	0.14	8	40	320
OPTN Membership Application for Histocompatibility Laboratories	141	0.21	30	2.5	75
OPTN Representative Form	1,760	0.02	37	0.25	9

OPTN Medical/Scientific Membership Application	10	0.3	3	0.75	2
OPTN Public Organization Membership Application	7	0.57	4	0.5	2
OPTN Business Membership Application	11	0.55	6	0.88	5
OPTN Individual Membership Application	8	0.88	7	0.25	2
OPTN Membership Application Surgeon or Physician Log ³	0	0	0	0	0
Primary Program Administrator Form	1,562	0.047	74	0.25	19
Primary Data Coordinator Form	1,760	0.03	52	0.13	7
Additional Surgeon and Physician Request Form	1,562	0.0736	115	1.17	135
HOPE Act Variance Request Form ⁴	68	0	0	1.33	0
Kidney Paired Donation Pilot Program (KPDPP) contact update form	159	0.33	53	1.63	86
Total = 22 forms	8,153		850		5,653

1. The numbers of respondents were updated with the data as of December 31, 2021, and reflect changes in members' statuses.
2. There were no Islet applications processed in 2021, hence no responses.
3. The OPTN Membership Application Surgeon or Physician Log is an optional form. The information can also be submitted by the OPTN member using a different format. The burden to complete is built into the organ application data.
4. There were no HOPE Act Variance Request forms processed in 2021, hence no responses.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of

the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,
Director, Executive Secretariat.

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